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July 12, 1999

1703 '99 SEP -9 10:04
2603 '99 AUG -3 P1:51

Jane Henney, M.D.
Commissioner
Food & Drug Administration
56500 Fishers Lane, Room 1471
Rockville, Maryland 20857

Dear Dr. Henney:

I hope very much that you will support the approval of the following claims:

- a. Saw palmetto and the symptoms of benign prostatic hyperplasia;
- b. Psyllium seed husks and the risk of heart disease;
- c. Folic acid and vitamins B6, B12, and E and the risk of cardiovascular disease.

In respect to all of the above, the beneficial effects of the stated supplements are well known, and have been well known for many, many years. To impede public understanding by restricting informative labeling as has been the practice of the FDA for many years seem to me to be indefensible.

I think particularly of the FDA rules which for so many years virtually prohibited over-the-counter sale of folic acid tablets. I remember this well, since at that time I had to purchase the folic acid on my trips to Canada, where it was sold freely. Now, decades later, the FDA mandates its addition to white flour. How many thousands of cases of spina bifida could have been avoided had there been a more open-minded attitude at the agency?

Similarly, the FDA for years closed its eyes on the beneficial effects of vitamin E as a means of preventing heart disease.

While the FDA "virtuously" restricts informative labeling on the many vitamins and food supplements, it allows drug manufacturers to tout the products with full-page ads in general readership magazines, despite known and serious side effects which appear in almost unreadable fine print on the next page or two.

99P-3029

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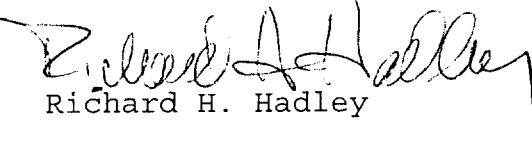
Penney, M.D.
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What would be extremely helpful, by contrast, could be action by the FDA to insure accurate labeling of vitamins and food products, so that a purchaser could have confidence that the contents were as represented.

This action, and that referred to above, would go far to show that the FDA has not "sold its soul" to the pharmaceutical industry.

Very truly yours,


Richard H. Hadley

RHH:df

cc: Senator Orrin Hatch
Senator Tom Harkin
Dr. Julian Whitaker

CROSS FILE SHEET

File Number: 99P-3029/c34

See File Number: 99P-3030/c34